

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: Not applicable

ACTIVE INGREDIENT: Not applicable

Study No: NIS-RFR-DUM-2009/1

Factors determining quality of life related to respiratory status according to gender of COPD patients followed by a pneumologist.
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Developmental Phase: Post-Marketing

Study Completion Date: 05/07/2010

Date of Report: 30/05/2011

OBJECTIVES:

To evaluate with sufficient precision and according to gender, the principal factors determining quality of life related to respiratory status as well as the demographic and clinical characteristics of moderate to very severe COPD out patients .

METHODS:

Multicenter, descriptive, cross-sectional study design.

RESULTS:

The study took place from September 2009 through July 2010: 446 patients were included in the study by 146 pneumologists and 430 patients, 42.6% men and 57.4% women, mean age 63.9 ± 11.3 years, were analyzed.

Women were younger (61.9 ± 11.3 vs. 66.6 ± 10.8 years, $p < 0.001$), had more frequently a lower BMI [≤ 21 kg/m²] (29.5 vs. 14.9%, $p < 0.001$), were more frequently unemployed (25.2 vs. 11.8%, $p < 0.001$) and lived more frequently alone (36.1 vs. 17.6%, $p = 0.002$).

Men were more frequently smokers or ex-smokers than women (97.8 vs. 84.6%, $p < 0.001$ Women had a lower cumulative tobacco use (37.0 ± 16.0 vs. 40.5 ± 19.0 packet-years, $p = 0.041$).

However, current smokers were more frequently women than men (44.1 vs. 30.2%, $p = 0.003$) and the daily consumption was similar (13.5 ± 7.0 vs. 14.2 ± 12.2 cigarettes, $p = \text{NS}$).

History of stroke/transient cerebral ischemia was significantly more frequent in men than in women (7.1 vs. 2.0%, $p = 0.009$). After adjusting on age and active smoking, women had 3.1 times less risk of having a history of stroke/transient cerebral ischemia.

The following concomitant diseases were less frequent in women: ischemic heart disease (5.7 vs. 24.4%, $p < 0.001$), lower limb arteriopathy (3.7 vs. 12.2%, $p = 0.001$), heart failure (2.9 vs. 8.4%, $p = 0.011$), dyslipidemia (16.7 vs. 26.0%, $p = 0.019$), alcoholism (3.3 vs. 8.8%, $p = 0.013$) and sleep apnea syndrome (4.1 vs. 13.3%, $p = 0.001$).

Conversely, the following concomitant diseases were more frequent in women: osteoporosis (19.6 vs. 2.8%, $p < 0.001$), anxiety disorders (29.4 vs. 16.8%, $p = 0.003$) and depression (19.0 vs. 4.6%, $p < 0.001$).

Among the patients suffering from anxiety disorders ($n = 102$), 53.0% were treated .

Women had less COPD risk factors than men (32.2 vs. 63.3%). Smoking was the only risk factor for 59.6% women. After adjusting on age and active smoking, women had 7.1 times less risk of being exposed to occupational pollutants (10.1 vs. 46.1%).

62.5% patients had at least one exacerbation in the preceding 12 months with no significant difference between men and women.

Women used inhaled short-acting β_2 agonists more frequently (53.1 vs. 40.0%, $p = 0.010$).

Dyspnea (MRC) was 3 or 4 for 113 patients (26.9%), with no significant difference between men and women. FEV1 (% of normal predicted), pre-bronchodilator, was higher in women than in men (52.2 ± 15.9 vs. $46.2 \pm 14.4\%$, $p < 0.001$).

GOLD COPD stages were lower in women than in men ($p = 0.026$, 54.6% stage 2 vs. 42.9%).

Quality of life related to respiratory status was assessed with the Saint George Hospital Questionnaire (SGRQ-C). Women had a lower score than men in all the dimensions of the SGRQ-C. Similarly, their total score was significantly lower (50.6 ± 19.5 vs. 45.4 ± 21.5 , $p = 0.019$).

A multivariate analysis showed that factors associated with the total SGRQ-C score were different in men and women.

Higher BOD index and HAD depression scores were factors associated with poorer quality of life in both men and women. Higher SGRQ-C total scores were associated with higher number of COPD treatments and chronic sputum in men and women, respectively.